

April 25, 1995

Steven R. Sumsion
General Counsel
Nature's Way Products, Inc.
10 Mountain Springs Parkway
Springville, Utah 84663

Re: Nutritional Support Statement Notification

Dear Mr. Sumsion:

This acknowledges receipt on March 21, 1995, of your letter, dated March 15, 1995, notifying the Food and Drug Administration (FDA) that your cranberry powder capsules dietary supplement product is being marketed with a statement of nutritional support on its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours

Margaret C. Binzer

Consumer Safety Officer

Regulatory Branch

Division of Programs

and Enforcement Policy

Office of Special Nutritionals

Center for Food Safety and Applied Nutrition